UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Q-MED AB, Plaintiff, vs. HA NORTH AMERICAN SALES AB, MEDICIS AESTHETICS HOLDINGS INC., and MEDICIS PHARMACEUTICAL CORP., Defendants.	:	12 Civ. 8071 (RJS)

REPLY DECLARATION OF PER LANGÖ

I, Per Langö, hereby declare as follows:

1. I submit this reply declaration, on personal knowledge, or, where indicated, on information and belief, in further support of Q-Med's motion for a preliminary injunction against HA North American Sales AB, Medicis Aesthetics Holdings Inc. and Medicis Pharmaceutical Corp. (collectively, "Medicis").

2. In particular, I submit this reply declaration to respond to certain arguments made by Medicis in papers submitted to the Court, including in the declarations of Doris Day, Vincent Ippolito and Mitchell Wortzman.

Competition Between The Restylane Family and Sculptra

3. I understand that Medicis contends that Sculptra does not compete directly with the Restylane family of products. For the reasons described below, Medicis' position is wrong, directly contradicted by Medicis' own documents and based on misleading uses of documents which do not actually bear on the relevant question.

4. As indicated in my initial declaration executed on November 2, 2012 ("Initial Decl."), Medicis' own Form 10-K filing for 2011 includes Medicis' clear and unambiguous admissions that Sculptra and the Restylane family compete directly. Initial Decl. Ex. D, pp. 12, 23. In Mr. Ippolito's declaration submitted by Medicis, he tries to parse the language of the reference to Sculptra at page 12 of the Medicis 10-K. *See* Ippolito Decl. ¶¶ 16-17. He ignores entirely, however, the reference to Sculptra at page 23, in the section describing material Risk Factors. That section states:

> We are experiencing **intense competition** in the dermal filler market. Other dermal filler products on the market include: Juvederm, Artefill, Belotero, Balance, Radiesse, Elevess, Hydrelle, LAVIV, Prevelle, Silk, and **Sculptra** Aesthetic. Patients may differentiate these products from our RESTYLANE and PERLANE branded products based on price, efficacy and/or duration, which may appeal to some patients.

Initial Decl. Ex. D, p.23 (emphasis added). The Form 10-K also lists Sculptra in the section labeled "Competition" and again describes the bases on which some patients may choose it instead of Restylane or Perlane. *Id.*, p.12.

5. As I also indicated in my initial declaration, Medicis' own "2013 Brand Plan" for the Restylane family describes Sculptra as being in the same market as, and competing for market share with, the Restylane family. Initial Decl. Ex. E.

6. In response, Mr. Ippolito attaches additional pages of the Brand Plan for 2013. He and Medicis argue that these pages, as well as other materials, show that Medicis is *most* concerned about competition from Juvederm. *See* Ippolito Decl. ¶ 15.

7. It is true that we and Medicis view Juvederm as the biggest competitive

threat to the Restylane family. Juvederm and Restylane each have market shares of about 35%, compared to about 10% for Sculptra. Initial Decl. Ex. E, p.4. But the fact that Juvederm is our biggest competitor obviously does not mean that we have no other direct competitors.

8. The FDA-approved indications for the two products are also very similar. I understand that Medicis acknowledges this fact but argues that it is irrelevant because of off-label use of Sculptra. *See* Wortzman Decl. ¶¶ 22-23. I am, frankly, stunned by the lack of importance that Medicis places on the FDA-approved uses of the product. I am aware that some off-label use can occur, but condoning it or encouraging it is illegal. FDA-approved indications follow a robust review, analysis and approval process by the FDA. Thus, the fact that Restylane and Sculptra are FDA-approved for almost identical indications is a vastly more reliable indicator of how the products are and should be used than Dr. Wortzman's speculations about off-label use.

9. Medicis also argues that Sculptra is different from Restylane in many ways, including that it utilizes a different technology and is marketed as providing a longer-lasting and more gradual effect. *See* Wortzman Decl. ¶¶ 13-20. I agree that these differences are present, but they have no bearing on whether the products compete directly.

10. The fact that the technology is different has no bearing on whether the products compete. Indeed, this is precisely why our contracts with Medicis provide one trigger for withholding consent to a change in control if the acquirer is engaged in a business involving a hyaluronic acid product and a *separate* trigger if the acquirer is

engaged in a business involving a directly competitive product that uses a different technology. The contracts themselves contemplate that products using different technology can compete directly.

11. Based on my ten years of experience with marketing Q-Med aesthetics products worldwide, I understand that patients are focused on the "visual outcome" that a dermal filler product provides. They are not focused on the science behind how different dermal fillers seek to achieve that visual outcome. A review of Restylane's and Sculptra's websites (attached as Exhibits F and G to my initial declaration) shows that the two products market precisely the same visual outcome. When a patient goes to a doctor seeking a particular visual outcome, such as smoothing away laugh lines, the doctor may recommend several dermal fillers that could achieve that visual outcome, including Restylane and Sculptra. The patient, in consultation with her doctor, will pick one. That, in a nutshell, is why the products compete directly.

12. I agree that the Restylane family and Sculptra have differentiating features that might cause a patient to pick one over the other. For example, Restylane products are marketed as providing more immediate results, while Sculptra is marketed as providing longer-lasting, but more gradual onset of results after a regimen of three to four treatments at three-week intervals. This does not mean that the products do not compete. Just the opposite: as Medicis' own Form 10-K filing explains, these differentiating features *are the basis of competition* insofar as they provide reasons that a patient might use Sculptra instead of a Restylane family product or vice versa. *See* ¶ 4, above. For example, the website excerpts attached as Exhibit C to Mr. Ippolito's declaration are self-

evidently marketing appeals to patients aimed at persuading patient to pick Sculptra *instead of* a product like Restylane because of Sculptra's different characteristics, such as the claims that Sculptra lasts longer, is more subtle and gradual, and requires fewer injections. Ippolito Decl. Ex. C.

13. I would also note that Medicis overstates the differentiating features. Although Medicis contends that Sculptra is marketed more for adding volume to the face and the Restylane family is marketed more for facial wrinkles, those differing marketing appeals are not at all stark. Sculptra's own website shows that Sculptra is marketed for correction of nasolabial folds. *See* http://www.sculptraaesthetic.com/consumer/where-is-sculptra-aesthetic-used.aspx. The American Society of Plastic Surgeons states on its website that Sculptra is used in the lower half of the face on laugh lines and nasolabial folds. *See* http://www.plasticsurgery.org/cosmetic-procedures/dermal-fillers.html?sub=Here%27s%20how%20they%20work#content. Medicis is currently conducting a study to show that Perlane, on the other hand, creates facial volume in a manner similar to Sculptra. Similarly, although Medicis contends that Sculptra is marketed as providing longer-lasting results, a recent clinical study shows that, with a refresh treatment, the effects of Restylane can be as long-lasting as Sculptra.

14. It may be the case that certain physicians, like Dr. Day and some of those cited in Mr. Ippolito's declaration, use both Restylane and Sculptra together on the same patients. Such use is not inconsistent with competition. I know, for example, that some physicians have used both Juvederm and Restylane on the same patients. For example, the website for the FIALA Aesthetics Day Spa in Florida contains an illustration about a

patient who was treated with a combination of Restylane and Juvederm. *See* http://day-spa-orlando.com/lip-injections-before-after. Notwithstanding such occasional complementary use, it is not disputed that Juvederm is Restylane's biggest competitor.

15. Moreover, to my knowledge, the use of Sculptra and Restylane on the same patient for the same treatment cycle is not common practice. (I would note that Dr. Day is one of only several thousand physicians who use our products in North America.) It would be much more expensive for patients (who all pay for dermal filler treatments directly out of pocket) to use both Sculptra and Restylane rather than only one or the other. Such use also would be contrary to Sculptra's warning label, which cautions against using Sculptra with other dermal fillers. *See* Initial Decl. Ex. H. Similarly, on the "frequently asked questions" section of a Q-Med practitioners website, Q-Med cautions against using Restylane together with other dermal fillers:

> Q: Can Restylane products be combined with other types of implant?
>
> A: Restylane products should not be used together with any other injectable implant, except for products within the Restylane range of products.

See http://www.q-medpractitioner.com/International/Restylane/FAQ. It may not be prudent for a physician to recommend or allow such complementary use because, among other reasons, if a patient is using two different dermal fillers, it may become more difficult to determine the cause and appropriate response to any adverse reactions.

16. The excerpts of documents relied upon by Medicis to attempt to show a lack of competition are extremely misleading. Medicis "urge[s] the Court to review [] in

detail" a Q-Med marketing study attached as Exhibit A to Mr. Ippolito's declaration, which Medicis contends is "highly revealing of Q-Med's view of the competitive landscape." Opp. Mem. at 12. Medicis presumably wants the Court to take note that Sculptra is hardly mentioned in this document. But, as the cover page makes clear, the brand assessment study is only about perceived benefits of certain hyaluronic acid (HA) products and covers only seven countries, not including the U.S. Given that Sculptra is *not* an HA product and is sold in only one of the seven countries covered by the study, it is hardly surprising that Sculptra is barely mentioned. The study, in short, is irrelevant to the issues at hand.

17. Similarly, Medicis relies on a third-party market assessment written in 2006, three years before Sculptra was FDA-approved for mainstream use. *See* Ippolito Decl. Ex. F. Since 2006, Valeant's predecessor, through its physician and consumer communication, moved Sculptra into mainstream positioning. Given the date of the report, it is not surprising that it does not refer to Sculptra as a mainstream product.

Loss of Market Share, Reputation and Good Will

18. As detailed in my initial declaration, Q-Med and the Restylane family of products would suffer irreparable harm if Medicis' exclusive rights to market and sell Q-Med's dermal filler products in North America were transferred to Valeant.

19. One of the concerns I expressed is that the Valeant sales force would not give Restylane products the same level of un-conflicted care and attention that they have received from Medicis. Mr. Ippolito's declaration confirms that my concern is well founded. He confirms that the post-merger sales force would market both Restylane and

Sculptra. *See* Ippolito Decl. ¶ 28.

20. It is self-evident that the marketing message delivered by a sales force carrying two competing dermal filler brands will be more muddled and less effective than the message delivered currently by the Medicis sales force, which carries only the Restylane family of dermal fillers. Doctors have finite time and attention to devote to interactions with sales representatives. Post-merger sales representatives, carrying Valeant's vast array of products, including two competing brands of dermal fillers, will have to make choices. Valeant will have every incentive to emphasize their own Sculptra brand (for which Valeant presumably receives all the economic benefits) over the Restylane family (as to which Valeant must share the economic benefits with Q-Med).

21. I take no comfort in Mr. Ippolito's blithe assertion that it would "make little sense" for Valeant to acquire Medicis and then not market Medicis' products effectively. *See id.* In fact, the Restylane family of products will be a tiny component of Valeant's portfolio. The Restylane family accounts for only 10% of Medicis' revenues currently, according to Medicis' CEO, *see* Shacknai Decl. ¶ 4, and will account for a much smaller percentage of Valeant's post-merger revenues. According to Valeant, the current Medicis product portfolio includes only 26 products, including only one dermal filler brand, while the Valeant product portfolio consists of more than 900 products. *See* Schiller Decl. ¶ 12. Thus, it is not at all irrational to conclude that Valeant would not give Restylane products the same level of un-conflicted care and attention that they have received from Medicis and that Valeant would have every incentive to favor their own competitive products over Restylane products.

Use and Disclosure of Confidential Information

22. Another of the concerns I expressed in my initial declaration is that transfer of Medicis' rights to Valeant would give Valeant, against our will, access to trade secret and other confidential information about the Restylane family of products.

23. In response, Dr. Wortzman, who serves with me on the Q-Med/Medicis Joint Steering Committee, submitted a declaration stating that Medicis "does not have, nor has it ever had, access to Q-Med's formulation and/or manufacturing trade secrets." Wortzman Decl. ¶ 26. Dr. Wortzman goes on to describe the types of manufacturing information about the Restylane family that has not been shared with Medicis. *Id.* ¶¶ 26-27. Dr. Wortzman's assertions are beside the point. By carefully limiting his testimony only to "manufacturing" information, Dr. Wortzman, quite conspicuously, side steps the real issue.

24. As detailed in my initial declaration, the confidential and trade secret information that would be disclosed to Valeant under the terms of our contracts with Medicis relates primarily to sales, marketing and business development matters, not manufacturing. *See* Initial Decl. ¶¶ 33-34. The Hyaluronic Acid Filler Brand Assessment study attached as Exhibit A to Mr. Ippolito's declaration is a good example of confidential marketing information that we share with Medicis.

25. Notably, Dr. Wortzman does not dispute my contentions that confidential sales, marketing and business development information is shared with Medicis or that Q-Med would have a contractual obligation to continue to share such information post-merger with Valeant.

26. Dr. Wortzman also does not – and cannot – dispute that disclosure of such information would give Valeant an unfair competitive advantage. Access to Q-Med's confidential information about Q-Med's possible future improvements and line extensions, its international marketing tactics, industry feedback it has received, and negative reactions to the Restylane family of products, would all be of obvious value to Valeant in marketing Sculptra. Also, I understand that Valeant has agreements with at least Sinclair Pharmaceuticals Ltd., pursuant to which Sinclair distributes Succeev and Sculptra in several markets. Obviously, Valeant's ability to share Q-Med's confidential information with outside entities which distribute a hyaluronic acid dermal filler product which indisputably competes directly with Restylane is also of great concern. Needless to say this concern is also true for Sculptra.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. ~~Executed~~ in Uppsala, Sweden on this 20 day of November, 2012

Per Langö